

MOBILE I.V. SYSTEMS, LLC23630 North 35th Dr. Glendale, AZ 85310

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JUL -1 2008**3. 510(k) Summary****Updated Summary Prepared:** 9 May 2008**Common Name:** Primary IV Fluid Administration Set**Classification Name:** Intravascular Administration Sets**Product Code:** FPA**Panel:** General Hospital and Personal Use**Device Classification:** II**Substantially Equivalent to:** The GVS Speedflow I.V. Administration Set with Easydrop Flow Regulator, K061115.

Description: Mobile I.V. Systems device, the Primary I.V. Fluid Administration Set consists of a tubing set with either a 0.2 µm or a 1.2µm GVS S.p.A filter, universal spike, all position drip chamber, two injection sites and a removable Easydrop flow regulator and is used as a fluid pathway for I.V. administration. Mobile I.V. will offer three models, which will allow the choice of 10drops/ml, 20 drops/ml, or 60 drops/ml. The Primary I.V. Fluid Administration Set was designed for Emergency Medical and Hospital settings and includes an all position drip chamber. The drip chamber allows the flow of liquid regardless of the position of the drip chamber.

Intended Use: Indicated as a single use, sterile device for use in gravity fed I.V. therapy or with a pressure infuser, when an extended fluid path is required for administration.

Risk Analysis Method- The FDA Guidance, Intravascular Administration Sets Premarket Notification Submissions [510(k)] was used for the Risk Analysis. The specific risks associated with this device were:

Identified Risk	Mitigation Measure
Device Malfunction	Bench Testing
Adverse Tissue Reaction	Biocompatibility
Infection	Sterilization
Improper Use	Labeling

Device Characteristics: In order to validate critical parameters of the product required to reduce risk, the following were performed:

Device Malfunction = Bench tests from ISO 8536-4, Infusion sets for single use, gravity feed

Section 6.2 Leak Testing

Section 6.3 Tensile Strength Testing

Section 6.8 Drip Chamber Fluid Delivery Testing

Section 6.10 Flow Rate Testing

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5. 510(k) Summary - continued

Bench Testing – continued

Priming Volume Testing, per internal test method.

Adverse Tissue Reaction = Biocompatibility

Biocompatibility testing was performed on the predicate device by GVS. All materials of construction including solvents are the same as this predicate device.

ISO 10993-10, Sensitization,
ISO 10993-11, Acute Systemic Injection,
ISO 10993-3, Haemocompatibility;
ISO 10993-5, Cytotoxicity MEM Elution;
ISO 10993-10, Intracutaneous Injection

Infection = Sterilization

Sterility Testing: Validation will be done according to ISO 11137:2006, with a sterility assurance level of 10^{-6} .

Sterile Packaging Testing: Validation will be done according to ISO 11607:2006, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.

Pyrogen Testing: Sets were validated according to USP 30:2007, <85> Biological Tests and Assays, Bacterial Endotoxin Test and USP30:2007, <161> Transfusion and Infusion Assemblies and Similar Medical Devices. The Kinetic Turbidimetric method was used.

Bacterial Retention Testing: Per industry recommendations, was performed on the predicate device, GVS Speedflow. The same filter is being used in the Mobile I.V. Systems Primary I.V. Fluid Administration Set.

The 0.2µm was tested and found to remove $\geq 99.9\%$ of the challenged organism, *Brevundimonas diminuta*.

The 1.2 µm was tested and found to remove $\geq 99.9\%$ of the challenged organism, *Candida Albicans*.

Summary: The materials and solvents of the Primary I.V. Fluid Administration Set are the same as in the predicate device, GVS Speedflow I.V. Set w/Easydrop Regulatory. K# 061115. The intended use and test results show or will show that the Mobile I.V. Systems Primary I.V. Fluid Administration Set is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Northwind Technologies, Corporation
Mobile I.V. Systems, LLC
C/O Ms. Dawn I. Moore
Regulatory Consultant
Dawn I. Moore
20171 Bowens Road
Manchester, Michigan 48158

Re: K080695
Trade/Device Name: I.V. Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 23, 2008
Received: May 23, 2008

Dear Ms. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K080695

Indications for Use Statement

510(k) Number: K080695 (to be assigned)

Device Name: I.V. Administration Sets

Indications for Use: Indicated as a single use, sterile device for use in I.V. therapy when an extended fluid path is required for administration.

Prescription Use: ✓
(Part 21 CFR 801 Subpart D)

or

Over-the-counter use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080695